### HAWAII ADMINISTRATIVE RULES

# TITLE 11

# DEPARTMENT OF HEALTH

# CHAPTER 114

# TESTING OF BLOOD, BREATH, AND OTHER BODILY SUBSTANCES FOR ALCOHOL CONCENTRATION

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<u>HISTORICAL NOTE:</u> Chapter 11-114 is based substantially upon Chapter 11-111. [Eff 11/27/81; am and comp 11/22/86; R DEC 30, 1993 ]

#### SUBCHAPTER 1

#### GENERAL PROVISIONS

- §11-114-1 <u>Purpose and applicability of chapter.</u>
  (a) The purpose of this chapter is to ensure that appropriate and uniform forensic alcohol testing is performed throughout the State of Hawaii so that legal criteria are met and reliable and accurate results are assured.
- (b) This chapter applies to individuals or laboratories who collect samples for or conduct forensic alcohol testing for the purpose of introduction of the alcohol test results into evidence in either civil or criminal proceedings under applicable State driving under the influence of alcohol statutes.
- (c) Laboratories, personnel, and breath alcohol testing facilities of the federal government are exempt from the provisions of this chapter except as required by federal statute or policy. [EffJDECJ30,J1993JJ] (Auth: HRS §321-161) (Imp: HRS §321-161; 286-2; 286-151; 286-152; 286-153; 286-154; 286-155.5; 286-158; 286-160; 286-162; 286-163; 286-171; 286-251; 286-254; 286-255; 286-256; 286-257; 286-258; 286-259; 291-4;

291-4.5; 291-5; 291-6; 291C-162; 321-1; 321-9; 321-10; 321-11; 321-13; 321-14; 321-18; 321-19; 321-20)

§11-114-2 <u>Compliance</u>. Nothing in this chapter shall be construed as limiting the introduction in any legal proceeding of relevant evidence of the alcohol concentration of a person's blood, breath, or other bodily substance not obtained in strict compliance with the requirements of this chapter provided that the evidence is offered in compliance with the Hawaii rules of evidence. [EffJDECJ30,J1993JJ] (Auth: HRS §321-161) (Imp: HRS §§321-161; 286-2; 286-151; 286-152; 286-153; 286-154; 286-155.5; 286-258; 286-251; 286-255; 286-256; 286-257; 286-258; 286-259; 291-4; 291-4.5; 291-5; 291-6; 291C-162; 321-1; 321-9; 321-10; 321-11; 321-13; 321-14; 321-18; 321-19; 321-20)

§11-114-3 <u>Severability</u>. Should any section, paragraph, sentence, clause, phrase, or application of this chapter be declared unconstitutional or invalid for any reason, the remainder of this chapter will not be affected. [EffJDECJ30,J1993JJ] (Auth: HRS §321-161) (Imp: HRS §§321-161; 321-9; 321-10; 321-11; 321-13)

#### SUBCHAPTER 2

#### BREATH ALCOHOL TESTING

§11-114-4 <u>Definitions.</u> As used in this subchapter:

"Alcohol" means ethyl alcohol.

"Accuracy test" means a test performed periodically using a simulator as an accuracy verification device to establish the accuracy of a breath alcohol testing instrument.

"Accuracy verification device" means a device or apparatus used to substantiate the accuracy of a breath alcohol testing instrument when a breath alcohol test or an accuracy test is conducted. These devices or

apparatus may be internal, external, integral parts of or attachments to breath alcohol instruments. Simulators (referred to by the NHTSA as "calibrating units for breath alcohol testers") are an example of one type of accuracy verification device, but other devices or apparatus approved by the NHTSA or the department for such use also qualify as accuracy verification devices.

"Accuracy verification test" means a test performed in conjunction with a breath alcohol test to verify the accuracy of the breath alcohol testing instrument using an accuracy verification device.

"Air blank" means that portion of a breath alcohol test in which the instrument draws in outside air to purge the instrument of the previous sample in the sample chamber.

"Alcohol concentration" means grams of alcohol per two hundred ten liters of breath, or terminology established by appropriate statute.

"Breath" means that portion of exhaled air that is considered to be end expiratory.

"Breath alcohol test" means a test to measure a person's breath for alcohol concentration which is conducted for forensic breath alcohol testing purposes and adheres to the criteria of this subchapter.

"Breath alcohol testing instrument" means a device for determining the alcohol concentration of a person's breath.

"Chief of police" means the law enforcement official charged with the enforcement of criminal laws in a jurisdiction in this State or an individual(s) authorized by that chief to represent the chief in matters pertaining to this subchapter. Authority granted under this subchapter to a "chief of police" applies only to personnel or breath alcohol testing locations in the chief's jurisdiction.

"Department" means the state department of health.

"Director of health" means the director of the state department of health or the director's representative(s). For purposes of this chapter this includes the DUI coordinator.

"DUI coordinator" means the director of health or the individual(s) authorized by the director of health to represent the director of health in matters pertaining to this chapter.

"License" means a document issued by the DUI coordinator or the chief of police to a supervisor or by the chief of police to an operator which grants permission for a supervisor or operator to practice in their field of breath alcohol testing.

"NHTSA" means the National Highway Traffic Safety Administration, a division of the Federal Department of Transportation.

"Operator" means a person who operates breath alcohol testing instruments and meets the requirement of section 11-114-10.

"Reference sample" means a sample of known alcohol concentration which can be used to determine the accuracy of a breath alcohol testing instrument.

"Supervisor" means a person who supervises operators of breath alcohol testing instruments and meets the requirements of section 11-114-9.
"Target value" means the result which should be obtained when an accuracy verification device (with reference sample as appropriate) is used in an approved testing procedure. [EffJDECJ30,J1993JJ] (Auth: HRS §321-161) (Imp: HRS §§321-161; 286-2; 286-151; 286-152; 286-153; 286-154; 286-155.5; 286-158; 286-160; 286-162; 286-163; 286-171; 286-251; 286-254; 286-255; 286-256; 286-257; 286-258; 286-259; 291-4; 291-4.5; 291-5; 291-6; 291C-162; 321-1; 321-9; 321-10; 321-18; 321-19; 321-20)

§11-114-5 <u>Instrument approvals.</u> (a) Breath alcohol tests shall be performed using a model of:

- (1) Breath alcohol testing instrument;
- (2) Breath alcohol testing instrument accessories; and
- (3) Accuracy verification device which are approved by the DUI coordinator.
- (b) The model specifications of NHTSA for evidential breath alcohol testing devices and for calibrating units (referred to in this subchapter as accuracy verification devices) for breath alcohol testers, as contained in 49 CFR, No. 242, pp. 48854-48865 and 49 CFR, No. 242, pp. 48865-48872, respectively, are integrated into and made a part of

this subchapter. Accordingly, those models of instruments, accessories, and calibrating units appearing in the "Conforming Products List of Evidential Breath Measurement Devices" as contained in 57 CFR, No. 46, pp. 8375-8376, and "Conforming Products List of Calibrating Units for Breath Alcohol Testers" as contained in 56 CFR, No. 54, pp. 1187-11819, are approved by the DUI coordinator for purposes of this subchapter.

- (c) The DUI coordinator may approve, in writing, modified versions of approved instruments, accessories, and accuracy verification devices. Approval will be contingent upon the continued performance of the instrument, accessory, or calibrating within the specifications set forth in subsection (b).
- (d) All breath alcohol testing devices approved by the director of health as of the effective date of this chapter shall remain approved unless the approval is specifically revoked by the director of health in writing. [EffJDECJ30,J1993JJ] (Auth: HRS §321-161) (Imp: HRS §321-161; 286-2; 286-151; 286-152; 286-153; 286-154; 286-155.5; 286-158; 286-160; 286-162; 286-163; 286-171; 286-251; 286-254; 286-255; 286-256; 286-257; 286-258; 286-259; 291-4; 291-4.5; 291-5; 291-6; 291C-162; 321-1; 321-9; 321-10; 321-18; 321-19; 321-20)
- §11-114-6 <u>Procedure approvals and measurement requirements.</u>
  (a) Except as provided in subsection (c), every breath alcohol testing procedure shall be approved by the DUI coordinator in writing and shall include, but not be limited to:
  - (1) Performance of an accuracy verification test with each breath alcohol test, using an approved accuracy verification device; and
  - (2) Inclusion of an air blank before and after each breath test.
- (b) With every breath alcohol test the following shall be met:
  - (1) The person to be tested shall not have ingested alcoholic beverages, eaten, smoked, or vomited for at least fifteen minutes before the breath alcohol test;
  - (2) The test shall be conducted using an approved

- instrument in conformance with section 11-114-5 and following an approved procedure as specified in subsection (a);
- (3) A copy of the approved breath alcohol testing procedure shall be accessible to the operator or supervisor;
- (4) The test shall be conducted by a person who is licensed as a breath alcohol testing supervisor or operator pursuant to section 11-114-9 or 11-114-10;
- (5) The result of the accuracy verification test shall be within the range of plus or minus 0.01, or plus or minus ten per cent of the target value, whichever is greater;
- (6) Breath alcohol and accuracy verification test results shall not be rounded up; and
- (7) Each breath alcohol test shall have been preceded by an accuracy test which meets the criteria of section 11-114-7, by not more than thirty-one days.
- (c) Any breath alcohol testing procedure approved by the director of health as of the effective date of this chapter shall continue to be approved and remain in effect unless superseded or revoked by the director of health in writing. [EffJDECJ30,J1993JJ] (Auth: HRS §321-161)(Imp: HRS §§321-161; 286-2; 286-151; 286-152; 286-153; 286-154; 286-155.5; 286-158; 286-160; 286-162; 286-163; 286-251; 286-251; 286-254; 286-255; 286-256; 286-257; 286-258; 286-259; 291-4; 291-4.5; 291-5; 291-6; 291C-162; 321-1; 321-9; 321-10; 321-18; 321-19; 321-20)
- §11-114-7 Accuracy tests. (a) Every accuracy test procedure shall be approved by the DUI coordinator in writing and shall include, but not be limited to the following requirements:
  - (1) The test shall be conducted by a supervisor;
  - (2) At least two different reference samples and an air blank shall be run with each accuracy test;
  - (3) Reference samples shall be chosen so that their target values are not less than 0.04gm alcohol /210 liters and not greater than

- 0.25qm alcohol /210 liters;
- (4) Reference sample target values shall differ from each other by at least 0.04gm alcohol /210 liters;
- (5) Reference sample test results which vary from the target value by more than plus or minus 0.01gm alcohol /210 liters or plus or minus ten percent, whichever is greater, shall be cause for the breath alcohol testing instrument used to be removed from service until the fault has been corrected; and
- (6) An accuracy test shall be performed on an operating instrument at intervals not to exceed thirty-one days.
- (b) Operating instruments do not include instruments in storage or being repaired. Upon return to operation from storage or repair an accuracy test shall be performed. [EffJDECJ30,J1993JJ] (Auth: HRS §321-161) (Imp: HRS §§321-161; 286-151; 286-152; 286-153; 286-154; 286-155.5; 286-158; 286-160; 286-162; 286-163; 286-171; 286-251; 286-254; 286-255; 286-256; 286-257; 286-258; 286-259; 291-4; 291-4.5; 291-5; 291-6; 291C-162; 321-1; 321-9; 321-10; 321-18; 321-19; 321-20)
- §11-114-8 Maintenance of instruments.

  Maintenance and repair of breath alcohol testing instruments shall be the responsibility of the agency using the instruments and shall not be at the expense of the department. [EffJDECJ30,J1993JJ] (Auth: HRS §321-161) (Imp: HRS §321-161; 321-1; 321-9; 321-10; 321-19)
- §11-114-9 <u>Supervisors.</u> (a) Supervisors of breath alcohol testing instruments shall be responsible for:
  - (1) The care of breath alcohol testing instruments;
  - (2) Insuring that instruments are maintained;
  - (3) Performing accuracy tests required by section 11-114-7;
  - (4) Performing or supervising, or both, breath

alcohol tests;

- (5) Reporting results of alcohol breath tests to appropriate governmental agencies as required by section 11-114-11;
- (6) Keeping records as required by section 11-114-12;
- (7) Training of operators when required; and
- (8) Insuring that the operators and instruments in the supervisor's charge adhere to the provisions of this subchapter.
- (b) No person shall serve as a supervisor without a valid license issued by the DUI coordinator or the chief of police.
- (c) A supervisor may practice only in the jurisdiction designated on the license.
- (d) Licensed supervisors are also considered to be licensed as breath alcohol testing operators.
- (e) A supervisor's license shall be effective for three years from date of issuance unless revoked by the issuer.
- (f) A written request for renewal of a supervisor license should be submitted to the DUI coordinator or the chief of police at least ninety days before the expiration of the current license.
- (g) A member of a law enforcement agency in the State may qualify for a supervisor's license by meeting one of the following requirements:
  - (1) Having successfully completed a training program described in subsection (h); or
  - (2) Having at least one year of experience in the operation, care, and maintenance of the approved breath alcohol testing instrument.
  - (h) Training programs for supervisors shall:
  - (1) Be conducted either by the DUI coordinator, the chief of police, the chief's representative(s) or, with the written approval of the DUI coordinator or the chief of police, by a representative(s) of the manufacturer of the breath alcohol testing instrument;
  - (2) Consist of a minimum of eight hours; and
  - (3) Be approved in writing by the DUI coordinator except as provided in subsection (j)(1).
  - (i) Supervisors may be licensed on additional

breath alcohol testing instruments upon completion of supplemental training approved in writing by the DUI coordinator.

- (j) Prior approvals:
- (1) Supervisor training programs approved by the director of health as of the effective date of this chapter shall continue to be approved and remain in effect unless superseded or revoked by the director of health in writing.
- (2) Persons who have been approved by the chief of police as supervisors as of the effective date of this chapter are deemed licensed as supervisors and shall continue to be licensed supervisors upon renewal of the license or until the expiration or revocation of the license. [EffJDECJ30,J1993JJ] (Auth: HRS §321-161) (Imp: HRS §321-161; 286-2; 286-151; 286-152; 286-153; 286-154; 286-155.5; 286-251; 286-254; 286-255; 286-256; 286-257; 286-258; 286-259; 291-4; 291-4.5; 291-5; 291-6; 291C-162; 321-1; 321-9; 321-10; 321-18; 321-19; 321-20)
- §11-114-10 Operators. (a) Operators of breath alcohol testing instruments shall be responsible for performing breath alcohol tests pursuant to section 11-114-6 and record keeping pursuant to section 11-114-12(b)(1).
- (b) No person shall serve as an operator unless the person has a valid supervisor's license pursuant to section 11-114-9(b), or has a valid operator's license issued by the chief of police.
- (c) An operator may only practice in the jurisdiction designated on the license.
- (d) An operator's license shall be effective for three years from the date of issuance unless revoked by the chief of police.
  - (e) Training programs for operators shall:
  - (1) Be conducted by the chief of police, the chief's representative(s) or, with the chief's approval, by a representative(s) of the manufacturer of the breath alcohol

testing instrument;

- (2) Consist of a minimum of four hours; and
- (3) Be approved in writing by the DUI coordinator except as provided in subsection (h)(1).
- (f) Operators may be licensed on additional breath alcohol testing instruments upon completion of training approved in writing by the DUI coordinator.
- (g) A member of a law enforcement agency in the State may qualify for an operator's license by meeting one of the following requirements:
  - (1) Having successfully completed training as specified in subsection (e);
  - (2) Having at least one year's experience in the operation of the approved breath alcohol testing instrument; or
  - (3) Exhibiting through examination or demonstration or both to the chief of police sufficient skill in the operation and interpretation of results of the approved testing instrument.
  - (h) Prior approvals:
  - (1) Operator training programs approved by the director of health as of the effective date of this chapter shall continue to be approved and remain in effect unless superseded or revoked by the director of health in writing.
  - (2) Persons who have been approved by the chief of police as operators as of the effective date of this chapter shall be licensed by the chief of police and shall continue to be licensed as breath alcohol testing operators upon renewal or until the expiration or revocation of the license.

[EffJDECJ30,J1993JJ] (Auth:HRS §321-161) (Imp: HRS §§321-161; 286-2; 286-151; 286-152; 286-153; 286-154; 286-155.5; 286-158; 286-160; 286-162; 286-163; 286-171; 286-251; 286-254; 286-255; 286-256; 286-257; 286-258; 286-259; 291-4; 291-4.5; 291-5; 291-6; 291C-162; 321-1; 321-9; 321-10; 321-18; 321-19; 321-20)

§11-114-11 <u>Reporting of results.</u> Results of breath alcohol tests when required shall be submitted

to the appropriate governmental agency or agencies. [EffJDECJ30,J1993JJ] (Auth: HRS §321-161) (Imp: HRS §321-161; 286-2; 286-151; 286-152; 286-153; 286-154; 286-155.5; 286-158; 286-160; 286-162; 286-163; 286-171; 286-251; 286-254; 286-255; 286-256; 286-257; 286-258; 286-259; 291-4; 291-4.5; 291-5; 291-6; 291C-162; 321-1; 321-9; 321-10; 321-18; 321-19; 321-20)

§11-114-12 <u>Records</u>. (a) Records shall be kept and maintained at the direction of a supervisor.

- (b) Records shall include information on:
- (1) Each breath alcohol test conducted;
- (2) Accuracy tests; and
- (3) Maintenance and repair of instruments used in the testing of breath for alcohol.
- (c) Records maintained pursuant to subsection (a) shall be retained by the jurisdiction for at least three years.
- (d) The DUI coordinator may require pertinent DUI testing records from testing facilities to be available for viewing by the department or to be forwarded to the department. [EffJDECJ30,J1993JJ] (Auth: HRS §321-161) (Imp: HRS §§321-161; 286-2; 286-151; 286-152; 286-153; 286-154; 286-155.5; 286-158; 286-160; 286-162; 286-163; 286-171; 286-251; 286-254; 286-255; 286-256; 286-257; 286-258; 286-259; 291-4; 291-4.5; 291-5; 291-6; 291C-162; 321-1; 321-9; 321-10; 321-18; 321-19; 321-20)
- §11-114-13 <u>Surveys of breath alcohol testing</u> <u>locations.</u> (a) The DUI coordinator may conduct onsite surveys of breath alcohol testing locations.
- (b) Written reports of surveys shall be sent by the DUI coordinator to the chief of police.
- (c) At no cost to the department, law enforcement jurisdictions in the State shall accept and test evaluation samples which the DUI coordinator may provide.
- (d) Results of these tests shall be promptly
  submitted to the DUI coordinator. [EffJDECJ30,J1993JJ]
  (Auth: HRS §321-161) (Imp: HRS §§321-161; 321-1; 321-9; 321-10)

- §11-114-14 <u>Supervisor and operator licenses.</u>
  (a) The DUI coordinator or chief of police may issue supervisor licenses or renewals.
- (b) The chief of police may issue operator licenses or renewals.
- (c) The chief of police should submit to the DUI coordinator in June of each year a roster of supervisors and operators, instrument(s) on which the individuals are licensed, and expiration dates for each supervisor or operator license. [EffJDECJ30,J1993JJ] (Auth: HRS §321-161) (Imp: HRS §321-161; 321-1; 321-9; 321-10; 321-19)
- §11-114-15 <u>Revocation or suspension of supervisor or operator licenses.</u> (a) A written notice of license revocation shall be issued by the DUI coordinator or the chief of police, whichever issued the license, to any supervisor or operator who:
  - (1) Obtains the license by deception;
  - (2) Falsifies breath alcohol test data or records; or
  - (3) Is no longer a member of a law enforcement agency within the State.
- (b) Failure of a supervisor to comply with the requirements of section 11-114-9 or an operator to comply with the requirements of section 11-114-10 may result in revocation of the license.
- (c) Any supervisor or operator whose license has been revoked under the provisions of this subchapter shall have a right to an administrative hearing in accordance with chapter 91, HRS. [EffJDECJ30,J1993JJ] (Auth: HRS §321-161) (Imp: HRS §321-161; 321-1; 321-9; 321-10; 321-19)

#### §11-114-16 Reserved.

#### SUBCHAPTER 3

TESTING OF BLOOD AND OTHER BODILY SUBSTANCES

§11-114-17 <u>Definitions.</u> As used in this

subchapter:

"Alcohol" means ethyl alcohol.

"Alcohol testing supervisor" means a person who supervises alcohol analysts and meets the requirements of section 11-114-19.

"Alcohol analyst" means a person who performs alcohol tests of blood or other bodily substances and meets the requirements of section 11-114-20.

"Alcohol concentration" means grams of alcohol per one hundred milliliters or cubic centimeters of blood, or terminology established by appropriate statute.

"Alcohol test" means a test to measure a person's blood or other bodily substance for alcohol concentration which is conducted for forensic alcohol testing purposes and adheres to the criteria of this subchapter.

"Blood" means whole blood.

"Department" means the state department of health.

"Director of health" means the director of the state department of health or the director's representative(s). For purposes of this chapter this includes the DUI coordinator.

"DUI coordinator" means the director of health or the individual(s) authorized by the director of health to represent the director of health in matters pertaining to this chapter.

"License" means a document issued by the department to a laboratory to perform alcohol tests.

"Other bodily substances" means a bodily sample other than blood or breath, such as urine, gastro-intestinal contents, and tissues.

"Performance evaluation sample" means an alcoholcontaining blood sample which is tested to assess the performance of the laboratory by comparison of the result with the target value.

"Reference sample" means a sample of known alcohol composition which can be used to determine the accuracy of an alcohol test instrument or procedure.

"Systematic error" means the difference between the mean of measured values and the target value; the difference may be expressed as per cent of the target value.

"Target value" means the result which should be obtained when a performance evaluation sample or

reference sample is used in an appropriate testing procedure. [EffJDECJ30,J1993JJ] (Auth: HRS §321-161) (Imp: HRS §321-161; 286-2; 286-151; 286-152; 286-153; 286-154; 286-155.5; 286-158; 286-160; 286-162; 286-163; 286-171; 286-251; 286-254; 286-255; 286-256; 286-257; 286-258; 286-259; 291-4; 291-4.5; 291-5; 291-6; 291C-162; 321-1; 321-9; 321-10; 321-11; 321-13; 321-14; 321-18; 321-19; 321-20)

- §11-114-18 <u>Laboratories.</u> (a) With the exception of the provisions in section 286-153, HRS, no laboratory shall perform alcohol tests pursuant to this subchapter without an alcohol testing laboratory license issued by the director of health.
- (b) A laboratory may qualify for and maintain a license to conduct alcohol testing if the director of health determines that the laboratory has met all of the following requirements:
  - (1) Is physically located in this State;
  - (2) Is licensed by the department as a clinical laboratory;
  - (3) Has adequate facilities, personnel, equipment, and instrumentation;
  - (4) Includes in its staff an alcohol testing supervisor who is qualified under section 11-114-19;
  - (5) Uses alcohol testing procedures approved in writing by the DUI coordinator or previously approved by the director of health as required by section 11-114-22 and demonstrates proficiency in those procedures;
  - (6) Has a quality assurance program approved in writing by the DUI coordinator which includes a chain of custody procedure; and
  - (7) Participates in and meets the requirements of a performance evaluation program for alcohol testing approved in writing by the DUI coordinator as required by section 11-114-21 at no cost to the department.
- (c) A license for a laboratory to perform alcohol tests shall be effective for up to twelve months from the date of issuance.
  - (d) The alcohol testing supervisor of a licensed

laboratory shall notify the DUI coordinator in writing within thirty days if the laboratory ceases operation or of any changes as they occur with regard to subsection (b) and shall also provide an updated list yearly of all employed alcohol analysts involved with alcohol testing.

(e) The director of health may revoke the license to perform alcohol testing of any laboratory which fails to conform to the requirements of this subchapter. [EffJDECJ30,J1993JJ] (Auth: HRS §321-161) (Imp: HRS §§321-161; 286-2; 286-151; 286-152; 286-153; 286-154; 286-155.5; 286-158; 286-160; 286-162; 286-163; 286-171; 286-251; 286-254; 286-255; 286-256; 286-257; 286-258; 286-259; 291-4; 291-4.5; 291-5; 291-6; 291C-162; 321-1; 321-9; 321-10; 321-11; 321-13; 321-14; 321-18; 321-19; 321-20)

§11-114-19 <u>Alcohol testing supervisors.</u> (a) The alcohol testing supervisor shall:

- (1) Be responsible for the validity of all alcohol tests conducted by the laboratory;
- (2) Oversee maintenance and repair of instruments and related accessories;
- (3) Ensure that only properly qualified alcohol analysts conduct alcohol tests;
- (4) Ensure that required records are kept;
- (5) Closely oversee alcohol testing operations in the laboratory; and
- (6) Ensure that the laboratory conforms to the requirements of this subchapter.
- (b) An alcohol testing supervisor shall meet one of the following minimum requirements:
  - (1) Have a doctorate in a physical, biological, or biomedical science from an accredited university and one year of subsequent fulltime professional supervisory or analytical experience in alcohol testing, clinical chemistry, toxicology, analytical biochemistry, or analytical chemistry;
  - (2) Have a master's degree in a physical, biological, or biomedical science from an accredited college or university and three years of subsequent full-time professional

- supervisory or analytical experience in the disciplines listed in paragraph (1);
- (3) Have a bachelor's degree in a physical, biological, or biomedical science from an accredited college or university and five years of subsequent full-time professional supervisory or analytical experience in the disciplines listed in paragraph (1);
- (4) Have seven years of experience as a professional alcohol analyst; or
- (5) Hold a clinical laboratory director's license pursuant to department of health rules.

  [EffJDECJ30,J1993JJ] (Auth: HRS §321-161)

  (Imp: HRS §§321-161; 286-2; 286-151; 286-152; 286-153; 286-154; 286-155.5; 286-158; 286-160; 286-162; 286-163; 286-171; 286-251; 286-254; 286-255; 286-256; 286-257; 286-258; 286-259; 291-4; 291-4.5; 291-5; 291-6; 291C-162; 321-1; 321-9; 321-10; 321-11; 321-13; 321-14; 321-18; 321-19; 321-20)

# §11-114-20 <u>Alcohol analysts.</u> (a) Alcohol analysts shall:

- (1) Perform alcohol testing of blood and other bodily substances;
- (2) Use testing procedures approved by the department; and
- (3) Keep records required by the alcohol testing supervisor.
- (b) Alcohol analysts who perform alcohol testing of blood and other bodily substances shall meet one of the following minimum requirements:
  - (1) Have a bachelor's degree from an accredited college or university with fifteen semester hours in college level chemistry courses;
  - (2) Have a clinical laboratory technologist or specialist (clinical chemistry) license from the department; or
  - (3) Have four years of experience as an alcohol analyst or as an analyst in analytical chemistry, clinical chemistry, or analytical biochemistry. [EffJDECJ30,J1993JJ] (Auth: HRS §321-161) (Imp: HRS §§321-161; 286-2;

286-151; 286-152; 286-153; 286-154; 286-155.5; 286-158; 286-160; 286-162; 286-163; 286-171; 286-251; 286-254; 286-255; 286-256; 286-257; 286-258; 286-259; 291-4; 291-4.5; 291-5; 291-6; 291C-162; 321-1; 321-9; 321-10; 321-11; 321-13; 321-14; 321-18; 321-19; 321-20)

- §11-114-21 <u>Performance evaluation samples.</u> (a) At no cost to the department, each laboratory licensed to perform alcohol testing shall participate in a performance evaluation program for alcohol testing which is approved in writing by the DUI coordinator.
- (b) The testing procedure used to test the performance evaluation samples shall meet the requirements of section 11-114-22.
- (c) For each twelve-month period starting from the laboratory license issue date, the results of a minimum of ten performance evaluation samples tested shall be within plus or minus 0.01 grams alcohol/100 milliliters, or plus or minus ten per cent, whichever is greater, of the target value of each sample.
- (d) Results of tests of performance evaluation samples and the corresponding target values should be sent to the DUI coordinator by the alcohol testing supervisor yearly. [EffJDECJ30,J1993JJ] (Auth: HRS §321-161) (Imp: HRS §321-161; 321-1; 321-9; 321-10)

#### §11-114-22 <u>Testing procedure approvals.</u>

- (a) Except as provided in subsection (f), only those blood alcohol testing procedures which have been approved in writing by the DUI coordinator shall be used.
- (b) For each blood alcohol testing procedure for which approval is requested the alcohol testing supervisor shall submit to the DUI coordinator for written approval:
  - (1) A detailed description of the laboratory's blood alcohol testing procedure;
  - (2) The laboratory's procedural validation data pursuant to subsection (c); and
  - (3) Pertinent documentation such as scientific

literature and manufacturer's specifications.

- (c) No blood alcohol testing procedure will be approved unless the following minimum requirements are met:
  - (1) An alcohol free sample shall produce a result which is less than 0.005 grams alcohol/100 milliliters;
  - (2) The standard deviation of the procedure shall not exceed 0.005 grams alcohol/100 milliliters at any sample concentration; and
  - (3) The systematic error shall not exceed plus or minus 0.005 grams alcohol/100 milliliters, or plus or minus five per cent, whichever is greater, of the target value. A minimum of ten measurements of each of three different sample concentrations shall be performed. The samples shall differ by at least 0.04 grams alcohol/100 milliliters in the range of 0.04 to 0.25 grams alcohol/100 milliliters.
- (d) Any modification of a previously approved alcohol testing procedure shall be approved by the DUI coordinator in writing before being put into use.
- (e) Alcohol testing procedures for post mortem sampling of other bodily substances, as they pertain to this chapter, shall be submitted to the DUI coordinator for written approval.
- (f) Procedures approved by the director of health as of the effective date of this chapter shall continue to be approved and remain in effect unless superseded or revoked by the director of health in writing.

  [EffJDECJ30,J1993JJ] (Auth: HRS §321-161) (Imp: HRS §\$321-161; 286-2; 286-151; 286-152; 286-153; 286-154; 286-155.5; 286-158; 286-160; 286-162; 286-163; 286-171; 286-251; 286-254; 286-255; 286-256; 286-257; 286-258; 286-259; 291-4; 291-4.5; 291-5; 291-6; 291C-162; 321-1; 321-9; 321-10; 321-11; 321-13; 321-14; 321-18; 321-19; 321-20)
- §11-114-23 <u>Sample collection procedures.</u> (a) The following safeguards shall be observed in the collection of a blood sample from a living individual for determination of its alcohol content:
  - (1) Blood shall be drawn only by a qualified

- person as specified in section 286-152, HRS.
- (2) The area of puncture for the drawing of blood shall be thoroughly cleansed and disinfected with a non-alcoholic aqueous solution of non-volatile antiseptic such as benzalkonium chloride or povidone-iodine.
- (3) Blood shall be drawn with an unused sterile dry needle. It may be collected into a evacuated specimen tube or withdrawn with a syringe and deposited into a clean, dry container. The container should contain an amount of anticoagulant and preservative approved by the DUI coordinator in writing. An example of an acceptable tube is a five ml draw glycolytic inhibition tube which contains about 10 mg potassium oxalate and about 12.5 mg sodium fluoride. Two containers of at least five ml each should be drawn, if possible. The container(s) shall be capped or stoppered and sealed.
- (4) Reusable equipment, if employed, shall not be cleaned with alcohol or kept in alcohol or other volatile organic solvent.
- (5) Each specimen shall be accompanied by the following information:
  - (A) Name of person from whom the blood was drawn;
  - (B) Date and time the blood sample was collected; and
  - (C) Name of person drawing blood.
- (6) Each specimen should be accompanied by the following information:
  - (A) Area of puncture from which the sample was drawn;
  - (B) Name and amount of preservative and anticoagulant, if any; and
  - (C) Name of witnessing officer.
- (7) A chain of custody shall be maintained.
- (b) While not in transit to a laboratory or under examination, all blood samples shall be kept refrigerated or frozen. [EffJDECJ30,J1993JJ] (Auth: HRS §321-161) (Imp: HRS §\$321-161; 286-2; 286-151; 286-152; 286-153; 286-154; 286-155.5; 286-158; 286-160; 286-162; 286-163; 286-251; 286-254; 286-255;

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286-256; 286-257; 286-258; 286-259; 291-4; 291-4.5; 291-5; 291-6; 291C-162; 321-1; 321-9; 321-10; 321-11; 321-13; 321-14; 321-18; 321-19; 321-20)
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- §11-114-24 <u>Testing of samples.</u> (a) With each batch of samples, the alcohol analyst shall use appropriate reference samples as specified in the procedure approved by the DUI coordinator in writing for that laboratory.
- (b) A copy of the written procedure shall be accessible to the alcohol analyst performing the test.
- (c) Samples should be tested within one week of receipt by the laboratory.
- (d) The remaining portion of the sample shall be refrigerated or frozen and retained for one year from the date of collection. [EffJDECJ30,J1993JJ] (Auth: HRS §321-161) (Imp: HRS §\$321-161; 286-2; 286-151; 286-152; 286-153; 286-154; 286-155.5; 286-158; 286-160; 286-162; 286-163; 286-171; 286-251; 286-254; 286-255; 286-256; 286-257; 286-258; 286-259; 291-4; 291-4.5; 291-5; 291-6; 291C-162; 321-1; 321-9; 321-10; 321-11; 321-13; 321-14; 321-18; 321-19; 321-20)
- §11-114-25 Reporting of results. Results of blood or other bodily substance alcohol tests, when required, shall be submitted to the appropriate governmental agency or agencies. [EffJDECJ30,J1993JJ] (Auth: HRS §321-161) (Imp: HRS §\$321-161; 286-2; 286-151; 286-152; 286-153; 286-154; 286-155.5; 286-158; 286-160; 286-162; 286-163; 286-171; 286-251; 286-254; 286-255; 286-256; 286-257; 286-258; 286-259; 291-4; 291-4.5; 291-5; 291-6; 291C-162; 321-1; 321-9; 321-10; 321-11; 321-13; 321-14; 321-18; 321-19; 321-20)
- §11-114-26 <u>Records</u>. (a) Records shall be kept and maintained at the direction of the alcohol testing supervisor. Records shall include information on:
  - (1) Each blood test conducted;
  - (2) Maintenance, or repair, or both of instruments used in the testing of blood or other bodily substances for alcohol; and

- (3) Results of laboratory performance evaluation programs.
- (b) Records maintained pursuant to this section shall be retained by the laboratory for at least three years.
- (c) The DUI coordinator may require pertinent DUI testing records to be available for viewing by the department or to be forwarded to the department. [EffJDECJ30,J1993JJ] (Auth: HRS §321-161) (Imp: HRS §\$321-161; 286-2; 286-151; 286-152; 286-153; 286-154; 286-155.5; 286-158; 286-160; 286-162; 286-163; 286-171; 286-251; 286-254; 286-255; 286-256; 286-257; 286-258; 286-259; 291-4; 291-4.5; 291-5; 291-6; 291C-162; 321-1; 321-9; 321-10; 321-11; 321-13; 321-14; 321-18; 321-19; 321-20)
- §11-114-27 <u>Laboratory surveys</u>. (a) The DUI coordinator may conduct on-site surveys of licensed laboratories. Written reports of surveys shall be sent by the DUI coordinator to the alcohol testing supervisor.
- (b) At no cost to the department, laboratories shall accept and test performance evaluation samples which the DUI coordinator may provide. Test results shall be submitted to the DUI coordinator. [EffJDECJ30,J1993JJ] (Auth: HRS §321-161) (Imp: HRS §321-161; 321-1; 321-9; 321-10)
- §11-114-28 <u>Laboratory licenses</u>. (a) The director of health may issue alcohol testing laboratory licenses or renewals.
- (b) License issuance is contingent upon compliance by the laboratory with the provisions of section 11-114-18.
- (c) An alcohol testing supervisor shall submit in writing a request to the director of health for a laboratory license to perform alcohol testing.
- (d) The alcohol testing license of a laboratory may be renewed upon written request from the alcohol testing supervisor. The director of health should receive the request at least two months before the expiration of the current license. [EffJDECJ30,J1993JJ]

(Auth: HRS §321-161) (Imp: HRS §§321-161; 321-9; 321-10; 321-11)

- §11-114-29 Revocation or suspension of laboratory licenses. (a) The director of health shall issue a written notice of revocation of the alcohol testing license of any laboratory which:
  - (1) Obtains the license falsely or deceitfully;
  - (2) Falsifies alcohol test data or records;
  - (3) Is no longer in operation;
  - (4) Has no qualified clinical laboratory director;
  - (5) Has no qualified alcohol testing supervisor;
  - (6) Is no longer licensed as a clinical laboratory by the department; or
- (7) Meets the stipulation of subsection (c) when issued a notice of alert or suspension. The notice shall list the specific reason(s) for the revocation and shall specify a schedule of corrective action, if the director of health determines that a schedule of corrective action is appropriate.
- (b) The director of health shall issue a written notice of alert or suspension to any laboratory which does not meet the provisions of this subchapter. The notice shall list specific laboratory features which require attention and shall specify a schedule of corrective action.
- (c) Failure to adhere to the schedule of corrective action in a notice of alert or suspension under subsection (b) shall result in the revocation of the laboratory alcohol testing license.
  [EffJDECJ30,J1993JJ] (Auth: HRS §321-161) (Imp: HRS §321-161; 321-9; 321-10; 321-20)
- §11-114-30 Reinstatement of laboratory licenses.
  (a) A laboratory may file a letter requesting reinstatement with the director of health within twenty days of receipt of a notice of license suspension or revocation.
- (b) Should no letter requesting reinstatement be filed with the director of health within twenty days of the receipt by a laboratory of a notice of suspension

or revocation, the decision of the director of health shall be final.

- (c) If a laboratory files a letter requesting reinstatement within twenty days of receipt of a notice of license suspension or revocation, the laboratory director shall have a right to an administrative hearing in accordance with chapter 91, HRS.
- (d) A laboratory may be issued a provisional license pending the decision of the hearing. A provisional license shall be effective no longer than one hundred eighty days or until the hearing is completed, whichever occurs first. [EffJDECJ30,J1993JJ] (Auth: HRS §321-161) (Imp: HRS §§321-161; 321-9; 321-10; 321-20)